



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,096	11/22/2000	Ernest G. Hope	D40182	4236
52323	7590	07/26/2006	EXAMINER	
JESSE A. HIRSHMAN, ESQ. 1722 MURRAY AVENUE PITTSBURGH, PA 15217			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/722,096	HOPE, ERNEST G.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 101-172 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 142-172 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 101-110, 118-120, 122-128 and 131-141 is/are rejected.
- 7) ☒ Claim(s) 111-117, 121, 129 and 130 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s).

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: HOPE, ERNEST G

Election/Restrictions

1. Applicant's new election is based on the presentation of claims 101-172 filed on 7/27/2005 after an initial office action on the merits was performed. A new restriction requirement was mailed 2/9/2006 to further separate patentable distinct inventions. Applicant's election without traverse of group II (claims 101-141) in the reply filed on 5/9/2006 is acknowledged.
2. The amendment filed 7/27/2005 is acknowledged and entered into the record. Accordingly, claims 2-100 are canceled without prejudice or disclaimer, and claims 101-172 are newly added.
3. Claims 1 and 101-172 are pending, claims 1, and 142-172 are withdrawn as being drawn to a non-elected invention.
4. Claims 101-141 are examined on the merits.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 102

6. The rejection of newly presented claims 101-110, 118-120, 122-128, and 131-141 as being anticipated by Lu *et al* under 35 USC § 102(b) is maintained for the reasons of record. Applicant argues that the cited reference does not anticipate the instantly claimed invention. Specifically applicant argues that the claims of the instant invention

Art Unit: 1643

have been amended or added to clarify and distinguish the instant invention from that of Lu *et al.* Applicant indicates that the instant invention is drawn to cells which are capable of attacking tumor associated vascular cells. Applicant indicates that Lu *et al.* does not “recognize that certain CIK cell populations can attack neo-vasculature”.

Applicant further contends that Lu *et al.* does not teach therapeutically effective amounts of cells or indicate “safe and effective” doses, and concludes that the cells as taught by Lu *et al.* are “considered unsafe for human use”. Applicant further argues that the instant invention has further defined a population of cells not contemplated by Lu *et al.* and fail to recognize that the their cells are able to attack tumor associated vasculature. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). Where applicant claims a composition in terms of a function, property or characteristic and the

Art Unit: 1643

composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102. The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product.

In the instant case, it appears that the invention of the instant application is simply a re-characterization of a previously unrecognized property of a cell line produced by Lu *et al*. The fact that Lu *et al* did not recognize that the cell line disclosed had the ability to attack tumor vasculature is immaterial because that property is deemed an inherent characteristic of the claimed cell line. In addition, just because a cell line is deemed unsafe for clinical use does not render the invention non-anticipatory. Rather, the standard is to determine whether the claimed invention was disclosed by another before the conception and reduction to practice of the instant invention. Moreover, as indicated above, and support by *In re Best*, there is no requirement that Lu *et al* had to recognize that the cell line in their possession was able attack tumor vasculature as now newly disclosed. Applicant has not indicated that the cell line as disclosed by Lu *et al* is any different (i.e. structural features) from that instantly claimed. The instant invention appears to take the additional step of characterizing additional feature of the cell (i.e. functional characteristics, and receptors located on the surface of the cell). Applicant has not provided any objective evidence to indicate that the cell line of Lu *et al* cannot attack tumor vasculature. Any statements presented are merely opinion of counsel, which has not been corroborated by any

Art Unit: 1643

objective evidence. Therefore, the newly characterized feature of attacking tumor associated vasculature is an inherent feature of the cell line as taught by Lu *et al.*

Applicant further contends that the means of making the cell via a closed system moves the cell one step closer to commercialization of the claimed invention. Applicant points to Figure 2 in the instant application to support the differences between the cells grown in a "closed system" vs. those grown in an open system. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Figure 2B in the instant application provides a comparison between cells grown in an open system (i.e. flask) vs. cells grown in a closed system (i.e. bioreactor) and its percent lysis. This figure does not provide any indication that the cells grown in the two different systems produce a structurally distinct cell line, only that they produce a cell line that is less efficient in lysis of cells. Again, as indicated above, applicant has not provided any objective evidence to indicate that the cell line instantly claimed is *materially* different or distinct from that taught by Lu *et al.* It appears that the methodology of making the cell line as disclosed by Lu *et al.* and that of the instant application are identical and would

Art Unit: 1643

therefore lead to the same product. Applicant has not provided any indication that the cell lines produced using the method of the instant application would not produce the cell line taught by Lu *et al.*

It should be noted that claims 118-120 are anticipated by Lu *et al* because the claims read on a cellular composition being analyzed by flow cytometry (see Lu *et al* 1688, for example)

Therefore, the rejection of claims under 35 USC 102(b) as being anticipated is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 101-110, 122-128, and 131-141 as being anticipated by Alvernas *et al* under 35 USC § 102(b) is maintained for the reasons of record. Applicant arguments are substantially similar to those already presented and argued, *supra*. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record for the same reasons set forth above (see paragraph 6).

Therefore, the rejection of claims under 35 USC 102(b) as being anticipated is maintained for the reasons of record.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 7/27/2005 and 5/6/2006.

Conclusion

8. Claims 101-110, 1189-120, 122-128, and 131-141 are not allowed. Claims 111-117, 121, 129-130 are objected to for depending on a rejected claim.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

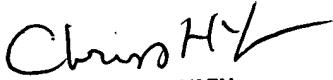
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
July 19, 2006


CHRISTOPHER H. YAEN
PRIMARY EXAMINER